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9 UNITED STATES DISTRICT COURT
10 CENTRAL DISTRICT OF CALIFORNIA
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13 In Re: NEXIUM
14 (ESOMEPRAZOLE) PRODUCTS
15 LIABILITY LITIGATION

Case No.: 12-ml-2404 DSF (SSx)

~~PROPOSED~~ **STIPULATED
PROTECTIVE ORDER**

16 This document relates to:

17 ALL CASES
18

[Discovery Document: Referred to
Magistrate Judge Suzanne H. Segal]

19
20 The parties hereto have stipulated and agreed to entry of a Protective Order
21 in this case. GOOD CAUSE APPEARING THEREFORE, it is hereby ORDERED
22 that a Protective Order shall be entered in this case, with the following terms,
23 conditions, and requirements:

24 **GOOD CAUSE STATEMENT**

25 Rule 26(c) of the Federal Rules of Civil Procedure permits entry of a
26 protective order “for good cause” shown. Among the reasons a protective order
27 may be entered is the protection of “a party or person from annoyance,
28 embarrassment, oppression, or undue burden or expense” (Fed R. Civ. P. 26(c)(1))

1 including the protection of "...a trade secret or other confidential research,
2 development, or commercial information" (Fed. R. Civ. P. 26(c)(1)(G)). The
3 parties agree that information and documents appropriately subject to protection
4 under Rule 26(c) may be sought, produced, or exhibited in discovery and that good
5 cause exists for entry of a protective order, as provided below.

6 A. Due to the nature of the products liability actions and claims
7 coordinated in this multi-district litigation (MDL) proceeding, it is anticipated that
8 documents and information may be sought, produced, or exhibited in discovery,
9 which are entitled to protection as trade secrets, and/or because they discuss
10 confidential and proprietary research and development, scientific, medical,
11 manufacturing, distribution, sales, marketing, and financial information concerning
12 Nexium® (esomeprazole), Prevacid® (lansoprazole) and/or any other proton pump
13 inhibitor manufactured or sold by the Defendants (*see* ¶ 1, *infra*). It is further
14 anticipated that documents reflecting communications concerning these matters
15 that are internal to an individual Defendant and/or involve agents or representatives
16 of an individual Defendant and third parties (such as regulators, suppliers,
17 distributors, marketers, and others involved in the approval, research, development,
18 production, distribution, marketing, and sale of a particular proton pump inhibitor)
19 may be sought, produced, or exhibited in discovery. Such documents and
20 information are commercially sensitive and derive value from their confidential,
21 proprietary, and/or trade secret nature. Competitors of one or more of the
22 Defendants could gain competitive advantage were they able to obtain information
23 identified in this paragraph as a result of its production for purposes of this
24 Litigation.

25 B. Documents sought, produced, or exhibited in discovery may also
26 include extensive proprietary information concerning one or more AstraZeneca
27 entities ("AstraZeneca"), McKesson Corporation ("McKesson") or Takeda
28 Pharmaceuticals U.S.A., Inc. ("Takeda") (collectively the "Defendants"), including

1 confidential and/or proprietary information concerning their respective: research
2 and development activities, plans, and information; formulation; manufacturing
3 processes, practices and procedures; distribution plans and data; sales plans and
4 data; marketing plans, research, activities and data; insurance coverage; budgets;
5 financial performance, information or results; business plans, strategies or
6 projections; acquisition offers or expressions of interest; proposed strategic
7 transactions or other business combinations or ventures; technical information and
8 specifications; studies or analyses by internal or outside experts; financial
9 information or results; tax data; assets and liabilities; competitive analyses;
10 personnel records and information; or any other such commercial, business or
11 other confidential and/or proprietary information. It is further anticipated that
12 documents reflecting communications concerning these matters that are internal to
13 an individual Defendant and/or involve representatives of an individual Defendant
14 and third parties (such as regulators, suppliers, distributors, marketers, and others
15 involved in the approval, production, marketing, and sale of a particular proton
16 pump inhibitor) may be sought, produced, or exhibited in discovery. Such
17 documents and information are commercially sensitive and derive value from their
18 confidential, proprietary, and/or trade secret nature. Those that compete with one
19 or more of the Defendants could gain competitive advantage were they able to
20 obtain information identified in this paragraph as a result of its production for
21 purposes of this Litigation.

22 C. The AstraZeneca entities and Takeda Pharmaceuticals U.S.A., Inc.,
23 parties to this MDL, are direct competitors with each other and other entities that
24 are not a party to this MDL proceeding. McKesson Corporation is a distributor of
25 pharmaceutical products and possesses not only its own confidential and
26 proprietary information, but also potentially the confidential and proprietary
27 information of the AstraZeneca entities, Takeda, and other manufacturers who are
28 competitors of the AstraZeneca entities and/or Takeda. If use and disclosure of the

1 trade secrets and/or confidential and proprietary information identified in
2 Paragraphs A and B above, are not (1) protected from public disclosure and (2)
3 limited in their use only for purposes of this Litigation (*see* ¶ 1 *infra*) in the manner
4 agreed herein, then the information could be used to gain competitive advantage
5 over one or more of the Defendants and/or third parties. The Defendants could be
6 irreparably harmed if this information is divulged to others or somehow misused
7 by the parties or non-parties. An unfettered ability to disclose or publish the
8 information described in Paragraphs A and B above, including but not limited to
9 the filing of documents in the public record, is likely to be harmful to the
10 commercial interests of one or more of the Defendants in this action. A protective
11 order is needed to facilitate good faith participation in the discovery process and to
12 prevent the Litigation from becoming a vehicle for improper purposes.
13 Accordingly, there exists good cause to enter this protective order to ensure
14 adequate protection against the wrongful use or disclosure of the foregoing
15 information and to protect the value associated with it.

16 D. It is further anticipated that private and/or personal information of plaintiffs
17 or persons not a party to this action, including private and/or personal health,
18 medical, employment, financial, and residence information, will be sought from
19 and/or produced or exhibited by the parties and/or third parties. Beyond the highly
20 personal nature of the information, such information is likely entitled to protection
21 by right of privacy, the Health Insurance Portability and Accountability Act
22 (HIPAA), the federal Food, Drug, & Cosmetic Act (FDCA), foreign privacy and
23 data protection laws, and/or other such legal protections. In the case of HIPAA,
24 for example, production of protected health information pursuant to subpoena,
25 discovery request, or other lawful process may be withheld until and unless the
26 holder of the information receives assurances that efforts have been made by a
27 party seeking such information to secure a “qualified protective order” that
28 prohibits the parties from using or disclosing the protected health information for

1 any purpose other than the litigation or proceeding for which such information was
2 requested; and requires the return to the covered entity or destruction of the
3 protected health information (including all copies made) at the end of the litigation
4 or proceeding. *See* 45 C.F.R. § 164.512, subd. (e). Also protected from disclosure
5 is information that would identify patients and/or persons associated with reporting
6 adverse events involving human drugs (excluding Plaintiff(s)), and research
7 subjects. *See* 21 C.F.R. §§ 20.63, 20.113, 45 C.F.R. §§ 160, 164. Documents that
8 originate from a foreign jurisdiction outside the United States that (1) are subject to
9 the protection of foreign privacy and data protection laws, and (2) which the
10 Producing Party reasonably believes in good faith to contain information about or
11 pertaining to a specific individual that can be linked to that individual and that
12 reveals race, ethnic origin, sexual orientation, political opinions, religious or
13 philosophical beliefs, trade union or political party membership or that concerns an
14 individual's health, is deemed highly sensitive and subject to protection that
15 requires limitation of the production of this information on an "attorneys' eyes
16 only" basis (*see* ¶ 16 *infra*). An unfettered ability to disclose or publish the
17 information described in this Paragraph, including but not limited to the filing of
18 documents in the public record, is legally prohibited and/or likely to be
19 embarrassing and/or harmful to the commercial, personal and/or privacy interests
20 of one or more of the parties or third parties. Accordingly, there exists good cause
21 to enter this protective order to ensure adequate protection against the wrongful use
22 or disclosure of the information described in this Paragraph.

23 E. It is anticipated that confidential, proprietary, or trade secret
24 documents and information belonging to third-parties governed by an obligation of
25 confidentiality or restricted use pursuant to law or agreement may be sought,
26 produced, or exhibited in discovery. And, in such instances, a protective order is
27 needed before a party or third party may disclose the protected information to
28 others for purposes of the Litigation. One or more third-parties could be

1 irreparably harmed if their trade secret, confidential, and/or proprietary information
2 and documents are divulged or somehow wrongly misused by the parties or non-
3 parties. An unfettered ability to disclose or publish such information, including but
4 not limited to the filing of documents in the public record, is likely to be harmful to
5 the commercial interests of the third-party owner of the information. Accordingly,
6 there exists good cause to enter this protective order to ensure adequate protection
7 against the wrongful use or disclosure of the foregoing information and to protect
8 the value associated with it.

9 F. Beyond seeking protection for the information described above, the
10 parties also seek to ensure that deposition testimony and written discovery
11 responses referencing or otherwise incorporating in whole or part any of this
12 information, are also entitled to protection from public disclosure or use for
13 purposes other than this Litigation.

14 G. The parties agree that entry of this stipulated protective order at the
15 start of discovery will facilitate a timely and efficient discovery process. For all
16 the foregoing reasons, the parties agree that good cause exists pursuant to Rule
17 26(c) of the Federal Rules of Civil Procedure for entry of this Stipulated Protective
18 Order (“Protective Order” or “Order”). Accordingly, the parties hereby
19 respectfully request that the Court enter this Order.

20 **PROTECTIVE ORDER**

21 1. This Order shall govern the above-captioned matter (the “MDL”),
22 including any appeal therefrom, and any other litigation brought by or on behalf of
23 any person against one or more AstraZeneca entities (“AstraZeneca”), McKesson
24 Corporation (“McKesson”) or Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”)
25 (collectively the “Defendants”) alleging personal injury, wrongful death, or other
26 damage arising from the purchase and/or ingestion of Nexium® (esomeprazole
27 magnesium), Prevacid® (lansoprazole) or any other proton pump inhibitor
28 manufactured or sold by the Defendants (collectively “the Litigation”).

1 2. As used in this Order, the term “Confidential Discovery Material”
2 means Documents, materials, or portions thereof, and information contained
3 therein, produced in the course of discovery of the Litigation that are designated
4 “Confidential” pursuant to the terms of this Protective Order, including Paragraphs
5 A through G above, by any party, person or original source of the document (the
6 “Producing Party”) to any other party or person (the “Receiving Party”) subject to
7 this Protective Order. (*See also* ¶ 8, *infra*.) The term “Confidential Personal
8 Information” means documents, material or information produced by the
9 Producing Party in the course of discovery of the Litigation that include and/or are
10 designated “Personal Information” or “Sensitive Personal Information-Attorneys
11 Eyes Only” pursuant to the terms of this Protective Order (see Paragraphs 15-17).
12 “Document” as used herein shall be interpreted broadly to include hard copy or
13 electronically stored information (“ESI”) including but not limited to: discovery
14 materials, writings, drawings, graphs, charts, photographs, sound recordings,
15 images, audio-visual materials and other data or data compilations stored in any
16 medium from which information can be obtained either directly or, if necessary,
17 after translation by the responding party into a reasonably usable form. This
18 Protective Order is applicable to all forms of discovery, including but not limited
19 to deposition testimony, deposition exhibits, answers to interrogatories, Documents
20 produced in response to requests for production, responses to requests for
21 admission, medical records, and any Documents recorded on computer disks or
22 removable storage media. As used herein, the terms “party” and “parties” refer to
23 those individuals or entities named as a party to any action pending in the
24 Litigation. The terms “person” and “persons” include parties and also any non-
25 party or third-party subject to this Protective Order.

26 3. This Protective Order is binding upon:

27 a. The parties to any action pending in the Litigation, including
28 their respective heirs, assigns, corporate parents, subsidiaries and affiliates,

1 and their respective attorneys, agents, experts, consultants, representatives,
2 officers, employees and others as set forth in this Order;

3 b. Any person who produces a Document in the Litigation
4 pursuant to this Protective Order;

5 c. Any person who obtains a Document produced or disclosed in
6 the Litigation pursuant to this Protective Order; and/or

7 d. Any person who signs the non-disclosure agreement in the form
8 of the Acknowledgement of Stipulated Protective Order
9 (“Acknowledgement”) attached as Exhibit 1 and incorporated herein by
10 reference.

11 4. The parties agree that Confidential Discovery Material and/or
12 Confidential Personal Information will be used only for the Litigation. Other than
13 described herein, Confidential Discovery Material and/or Confidential Personal
14 Information will not be used for any other purpose, including other litigation, and
15 shall not be disclosed to any person or governmental agency or otherwise made
16 public except in compliance with the terms of this Order, or by determination of
17 the Court.

18 5. This Order is HIPAA-compliant pursuant to 45 C.F.R. § 164.512
19 (e)(1)(v). The parties agree that Confidential Discovery Material and/or
20 Confidential Personal Information will be used only for the Litigation, including
21 Documents that contain Protected Health Information (PHI) and individually
22 identifiable health information that is protected from unauthorized disclosure by
23 the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”),
24 codified in 45 C.F.R. §§ 160, 164.

25 6. Any pleadings, discovery responses, statements, declarations, drafts,
26 copies, photographs, depictions, excerpts, and notes concerning or other
27 information generated from an inspection of a Document that quotes, incorporates,
28 reflects or otherwise includes, in whole or in part, Confidential Discovery Material

1 and/or Confidential Personal Information shall be treated in the same manner as
2 the Document bearing the designation.

3 7. Any person subject to this Protective Order who receives any
4 Confidential Discovery Material and/or Confidential Personal Information in the
5 course of discovery in the Litigation shall not disclose such Confidential Discovery
6 Material and/or Confidential Personal Information to anyone else except as
7 expressly permitted by this Protective Order.

8 8. The Producing Party may designate as Confidential Discovery
9 Material and/or Confidential Personal Information any Document that it in good
10 faith believes constitutes non-public information that is used by the Producing
11 Party in, or pertaining to, its business that would not normally be disclosed to third
12 parties or, if disclosed, would require third parties to maintain the information in
13 confidence. Information subject to a confidentiality designation may include, but
14 is not limited to information described in Paragraphs A through G in the Good
15 Cause Statement above, including:

16 a. Documents and information entitled to protection as trade
17 secrets, and/or because they discuss confidential and proprietary research
18 and development, scientific, medical, manufacturing, distribution, sales,
19 marketing, and financial information concerning Nexium® (esomeprazole),
20 Prevacid® (lansoprazole) and/or any other proton pump inhibitor
21 manufactured or sold by the Defendants (*see* ¶ A, *supra*);

22 b. Proprietary information concerning one or more Defendants,
23 including confidential and/or proprietary information concerning their
24 respective: research and development activities, plans, and information;
25 formulation; manufacturing processes, practices and procedures; distribution
26 plans and data; sales plans and data; marketing plans, research, activities and
27 data; insurance coverage; budgets; financial performance, information or
28 results; business plans, strategies or projections; acquisition offers or

1 expressions of interest; proposed strategic transactions or other business
2 combinations or ventures; technical information and specifications; studies
3 or analyses by internal or outside experts; financial information or results;
4 tax data; assets and liabilities; competitive analyses; personnel records and
5 information; or any other such commercial, business or other confidential
6 and/or proprietary information (*see* ¶ B, *supra*);

7 c. Private and/or personal information of plaintiffs or persons not
8 a party to this action, including private and/or personal health, medical,
9 employment, financial, and residence information, and information that
10 would identify patients and/or persons associated with reporting adverse
11 events involving human drugs (excluding Plaintiff(s)), and research subjects
12 (*see* ¶ D, *supra*);

13 d. Documents that originate from a foreign jurisdiction outside the
14 United States and (1) are subject to the protection of foreign privacy and
15 data protection laws, and (2) which the Producing Party reasonably believes
16 in good faith to contain information about or pertaining to a specific
17 individual that can be linked to that individual and that reveals race, ethnic
18 origin, sexual orientation, political opinions, religious or philosophical
19 beliefs, trade union or political party membership or that concerns an
20 individual's health (*see* ¶ D, *supra*); and

21 e. Confidential, proprietary, or trade secret documents and
22 information belonging to third-parties governed by an obligation of
23 confidentiality or restricted use pursuant to law or agreement (*see* ¶ E,
24 *supra*).

25 9. The Producing Party may designate a Document containing
26 Confidential Discovery Material by stamping or otherwise clearly marking the
27 Document "Confidential" in such a manner that will not interfere with legibility or
28 audibility.

1 10. To the extent that Confidential Discovery Material stored or recorded
2 in the form of electronic or magnetic media (including, but not limited to:
3 information, files, databases or programs stored on any digital or analog machine-
4 readable device, computers, Internet sites, discs, networks, or tapes (collectively
5 referred to as "Electronic Discovery Material")) is produced in such form, the
6 Producing Party may designate the Electronic Discovery Material as
7 "Confidential" by cover letter referring generally to the Electronic Discovery
8 Material, or by designation in the accompanying load file, or by stamping or
9 marking the production media containing the Documents as "Confidential."
10 Whenever a party or other person receives Electronic Discovery Material subject to
11 this Order and reduces the Electronic Discovery Material to hardcopy or image
12 form, that party shall mark the hardcopy or image form with the appropriate
13 confidentiality designation.

14 11. All depositions or portions of depositions taken in this action that
15 contain Confidential Discovery Material and/or Confidential Personal Information
16 may be designated "Confidential" and thereby obtain the protections accorded
17 under this Protective Order. Confidentiality designations for depositions shall be
18 made either on the record or by written notice to the other party within 30 days of
19 receipt of the final transcript. Unless otherwise agreed, depositions shall be treated
20 as "Confidential" through the 30-day period following receipt of the transcript.
21 The deposition of any witness (or any portion of such deposition) that encompasses
22 Confidential Discovery Material or Confidential Personal Information shall be
23 taken only in the presence of persons who are bound or have agreed to be bound by
24 this Order and who have executed the attached Acknowledgement of Stipulated
25 Protective Order.

26 12. Documents produced by a third party shall be treated as Confidential
27 Discovery Material and/or Confidential Personal Information for thirty (30)
28 calendar days after production. During this period any party may designate such

1 Documents as Confidential pursuant to the terms of this Order. Any party
2 designating third party information as "Confidential" shall have the same rights as
3 a Producing Party under this Order with respect to such information.

4 13. Confidential Discovery Material and/or Confidential Personal
5 Information includes information that would identify patients and/or persons
6 associated with reporting adverse events involving human drugs (excluding
7 Plaintiff(s)), and research subjects. See 21 C.F.R. §§ 20.63, 20.113, 45 C.F.R. §§
8 160, 164. Defendants shall not be compelled to disclose this identifying
9 information and a defendant may redact this identifying information from
10 discovery material before production, provided, however, that such defendant shall
11 maintain an un-redacted copy of such discovery material for any further review by
12 the Court.

13 14. Pursuant to 45 C.F.R. § 164.512 (e)(1)(v), the parties may exchange
14 and use for lawful purposes, including motions and trial, Documents containing
15 Confidential Discovery Material and/or Confidential Personal Information on the
16 following conditions: (1) that the parties are strictly prohibited from using or
17 disclosing the records for any purpose other than the Litigation; and (2) at the
18 conclusion of the Litigation, or upon the expiration of the period during which an
19 appeal may be sought, whichever comes later, each party will return the records
20 received from the other or destroy the records received from the other, including
21 any and all copies in their possession, and certify its compliance with this
22 paragraph. Information disclosing the identity of any patients and/or voluntary
23 reporters that are not redacted pursuant to Paragraph 13 shall be treated as
24 Confidential Discovery Material and/or Confidential Personal Information,
25 regardless of whether the Document containing such names is designated as
26 Confidential Discovery Material or Confidential Personal Information. The
27 person(s) identified in such records shall not be contacted, either directly or
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1 indirectly, based on information so disclosed without the express written
2 permission of the Producing Party, or by order of Court.

3 15. Any Document produced by a party in discovery that (1) originates
4 from a foreign jurisdiction outside the United States and is subject to the protection
5 of foreign privacy and data protection laws, and (2) contains information about or
6 pertaining to a specific individual that can be linked to that individual, may be
7 designated as "Personal Information" by the Producing Party. The Producing Party
8 shall effectuate the designation by stamping or otherwise clearly marking the
9 Document "Personal Information" in such a manner that will not interfere with
10 legibility or audibility.

11 16. Any Document produced by a party that originates from a foreign
12 jurisdiction outside the United States that (1) is subject to the protection of foreign
13 privacy and data protection laws, and (2) which the Producing Party reasonably
14 believes in good faith to contain information about or pertaining to a specific
15 individual that can be linked to that individual and that reveals race, ethnic origin,
16 sexual orientation, political opinions, religious or philosophical beliefs, trade union
17 or political party membership or that concerns an individual's health, may be
18 designated as "Sensitive Personal Information-Attorneys Eyes Only" by the
19 Producing Party. The Producing Party shall effectuate the designation by stamping
20 or otherwise clearly marking the Document "Sensitive Personal Information-
21 Attorneys Eyes Only" in such a manner that will not interfere with legibility or
22 audibility.

23 17. To the extent that Confidential Personal Information is stored or
24 recorded on Electronic Discovery Material, and is produced in such form, the
25 Producing Party may designate the Electronic Discovery Material as "Personal
26 Information" or "Sensitive Personal Information-Attorney Eyes Only" by cover
27 letter referring generally to the Electronic Discovery Material, or by designation in
28 the accompanying load file, or by stamping or marking the production media

1 containing the Documents as “Personal Information” or “Sensitive Personal
2 Information-Attorney Eyes Only.” Whenever a party or other person receives
3 Electronic Discovery Material subject to this Order and reduces the Electronic
4 Discovery Material to hardcopy or image form, that party shall mark the hardcopy
5 or image form with the appropriate Confidential Personal Information designation.

6 18. If at any time a party realizes that previously undesignated Documents
7 should be designated as Confidential Discovery Material and/or Confidential
8 Personal Information, the party may so designate by advising all other parties in
9 writing. The designated Documents will thereafter be treated as Confidential
10 Discovery Material and/or Confidential Personal Information pursuant to this
11 Protective Order. Upon receipt of such designation in writing, each party shall
12 take reasonable and appropriate action to notify any and all persons to whom the
13 party provided the Documents of the protected status of the newly designated
14 Confidential Discovery Material and/or Confidential Personal Information, and to
15 retrieve same from any person to whom the party has provided it who is not
16 permitted by this Protective Order to be in possession of such information.

17 19. The terms of this Order shall in no way affect the right of any person
18 (a) to withhold or redact information on the alleged grounds of immunity from
19 discovery such as, for example, attorney-client privilege, work product or privacy
20 rights of such third parties as patients, physicians, clinical investigators, employees
21 or reporters of claimed adverse reactions, in accordance with domestic or foreign
22 data protection and privacy laws; (b) to withhold or redact those portions of
23 documents that contain information relating to products not relevant to the
24 Litigation; or (c) to withhold or redact information on alleged grounds that such
25 information is neither relevant to any claim or defense nor reasonably calculated to
26 lead to the discovery of admissible evidence.

27 20. To facilitate and expedite discovery, the Defendants may, at their
28 option, produce Documents containing commercially sensitive and proprietary

1 information regarding products not relevant to the Litigation (“Other Drug
2 Information”) without redacting such information.

3 a. The Receiving Party and any other person who receives
4 Documents through the Receiving Party will only use Documents containing
5 Other Drug Information for the information contained therein relating to the
6 products at issue in the Litigation, and will use such Documents and
7 information for the sole purpose of the Litigation.

8 b. The Receiving Party or any other person who receives
9 Documents through the Receiving Party will not use Documents containing
10 Other Drug Information, or any information derived therefrom, for any
11 purpose following the conclusion of the Litigation.

12 c. At any point during the pendency of the Litigation, the
13 Producing Party Defendant may at its option redact Other Drug Information
14 or clawback a Document containing Other Drug Information that has been
15 produced and substitute a redacted version of the Document.

16 d. If the Producing Party Defendant desires to clawback a
17 Document containing Other Drug Information, they will provide notice to
18 the Receiving Party identifying the Document being clawed back and will
19 also provide a new version of the Document in which the commercially
20 sensitive or proprietary Other Drug Information has been redacted. Upon
21 receipt of the new redacted version of the Document, the Receiving Party (i)
22 will return or destroy the previous version of the Document; (ii) will not use
23 the previous version for any purpose, and (iii) will ensure it retrieves any
24 and all copies of the Document from any person who received Documents
25 through the Receiving Party.

26 21. Inadvertent production or other disclosure of Documents subject to
27 work-product immunity, the attorney-client privilege, joint defense privilege, or
28 other legal privilege that protects information from discovery shall not constitute a

1 waiver of the immunity, privilege, or other protection, provided that the Producing
2 Party notifies the Receiving Party in writing when it becomes aware of such
3 inadvertent production. Upon notification, the Receiving Party shall immediately
4 return, sequester or destroy the inadvertently-produced Document and all copies as
5 well as notes and work product reflecting the contents of such materials. The
6 Producing Party shall immediately update its privilege log to include the
7 inadvertently produced Document(s), and will produce a replacement production
8 for the clawed back Document(s) as well as updated privilege log information for
9 the Document(s) within seven (7) days of the date they notified the Receiving
10 Party of the inadvertent Production. If only a portion of the Document is
11 privileged, the Producing Party shall provide a new version of the Document in
12 which the privileged information has been redacted. No further use or disclosure
13 shall be made of the inadvertently-produced Document(s), and the Receiving Party
14 shall take all reasonable and appropriate steps to retrieve the Document(s), and all
15 copies, from any person who has received Documents through the Receiving Party,
16 until the claim, if any, is resolved. Any party who objects to the Producing Party's
17 claim of privilege shall serve upon counsel for interested parties a written notice
18 stating with particularity all good faith litigation driven reasons for the objection.
19 The parties shall make good faith efforts to resolve any dispute with opposing
20 counsel, including meeting and conferring with counsel for the Producing Party,
21 regarding the designation of any inadvertently produced Document(s). If
22 agreement cannot be reached, the dispute will be submitted to the Court in
23 accordance with Central District Local Rule 37. Upon agreement of the parties or
24 order of the Court that the Documents are in fact protected, the Receiving and/or
25 challenging party shall immediately return or destroy the inadvertently produced
26 Documents, any copies from any litigation support or other database, and any notes
27 or work product reflecting the contents of such materials. The parties shall have
28 the benefit of all limitations on waiver afforded by the Federal Rules of Civil

1 Procedure and Federal Rules of Evidence 501 and 502. Failure to assert privilege
2 in the Litigation as to one Document shall not be deemed to constitute a waiver of
3 the privilege of any other Document allegedly so protected, even involving the
4 same subject matter. Any inadvertent disclosure of privileged information shall
5 not operate as a waiver in any other federal or state proceeding, and the parties'
6 agreement regarding the effect of inadvertent disclosure of privileged information
7 shall be binding on non-parties.

8 22. Except for Documents designated as "Sensitive Personal Information-
9 Attorneys Eyes Only" for which disclosure is governed by Paragraph 23 and as
10 otherwise expressly provided by this Order, Confidential Discovery Material
11 and/or "Confidential Personal Information" (including Documents designated as
12 "Personal Information") shall not be disclosed to any person, except as follows:

13 a. Counsel of record for the parties in the Litigation, including any
14 paralegal, clerical, and other staff employed by counsel for work on the
15 Litigation;

16 b. Where produced by a plaintiff, in addition to the persons
17 described in subsection (a) of this section, Defendants' in-house counsel,
18 paralegals and outside counsel, including any attorneys employed by or
19 retained by Defendants' outside counsel who are assisting in connection
20 with this Litigation, and the paralegal, clerical, and other staff employed or
21 retained by Defendants' outside counsel;

22 c. Employees of the parties' outside counsel or third-party
23 vendors involved solely in one or more aspects of reviewing, organizing,
24 filing, coding, converting, storing or retrieving Documents or designating
25 programs for handling Documents connected with the Litigation, including
26 the performance of such duties in relation to a computerized litigation
27 support system;

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1 d. With respect to a specific Document, the Document's author,
2 addressees, and any other person shown on the face of the Document to have
3 received a copy;

4 e. Any witness, who counsel for a party in good faith believes
5 may be called to testify at trial or deposition in the Litigation, provided such
6 person has first executed the Acknowledgement of Stipulated Protective
7 Order; however, if the witness is currently an employee, officer, director,
8 contractor, subcontractor or consultant of an entity that is presently engaged
9 or is planning to be engaged in the research, development, distribution,
10 manufacture or sale of any product that competes with or is or is in the same
11 therapeutic class with any product researched, developed, manufactured or
12 sold by the Producing Party, the party seeking the testimony must first
13 comply with Paragraph 25 below, and receive written consent of counsel for
14 the Producing Party, or obtain an order from the Court permitting the
15 disclosure to said witness;

16 f. Outside consultants, outside experts, or other persons providing
17 advice to counsel (including mock juries), who have been retained for the
18 purpose of assisting counsel in the Litigation, provided such persons have
19 first executed the attached Acknowledgement of Stipulated Protective Order;

20 g. Insurers and indemnitors to the extent reasonably necessary to
21 defend and evaluate the claims;

22 h. Plaintiffs' counsel of record in any action transferred to the
23 MDL, provided that a Protective Order with similar confidentiality
24 protections has been entered in each case and signed by plaintiffs' counsel to
25 whom disclosure is sought;

26 i. Official court reporters; and

27 j. The Court, agreed mediators, and their support personnel.
28

1 23. Documents designated as “Sensitive Personal Information-Attorneys
2 Eyes Only” may only be disclosed to:

3 a. Outside counsel for the parties to the Litigation, which includes
4 undersigned Plaintiffs’ counsel, who are actively engaged in the lawsuit
5 including any paralegal, clerical, and other staff employed by outside
6 counsel for work on the Litigation;

7 b. Where produced by a plaintiff, Defendants’ in-house counsel
8 and paralegals;

9 c. A witness at any deposition in the Litigation who is an
10 employee of the Producing Party or who authored or was copied on the
11 Document;

12 d. Outside consultants, outside experts, or other persons providing
13 advice to counsel (including mock juries), who have been retained for the
14 purpose of assisting counsel in the Litigation, provided such person has first
15 executed the Acknowledgement of Stipulated Protective Order;

16 e. Official court reporters;

17 f. The Court, agreed mediators, and their support personnel; and

18 g. Plaintiffs’ counsel of record in any action transferred to the
19 MDL, provided that a Protective Order with similar confidentiality
20 protections has been entered in each case and signed by plaintiffs’ counsel to
21 whom disclosure is sought.

22 24. Prior to any disclosure of Confidential Discovery Material or
23 Confidential Personal Information, to any person referred to in subparagraphs (b),
24 (e) or (f) of Paragraph 22 or subparagraph (d) of Paragraph 23 above, the person
25 shall be provided by counsel with a copy of this Protective Order and shall sign the
26 Acknowledgement of Stipulated Protective Order attached as Exhibit 1 hereto.
27 The Acknowledgement states that the person agrees to be bound by the terms of
28 the Protective Order. All Acknowledgements will be maintained throughout the

1 Litigation by the attorneys obtaining them. At the conclusion of the Litigation,
2 upon a showing of good cause and necessity, any party may seek an order
3 requiring production of the Acknowledgements, but nothing in this Protective
4 Order is intended to modify or shift any burden of proof or privilege relating to the
5 motion or authorize discovery of experts or their identities.

6 25. Except as set forth in this paragraph, Confidential Discovery Material
7 and Confidential Personal Information produced by the Defendants may not be
8 provided or disclosed to anyone who is currently an employee, officer, director,
9 contractor, subcontractor or consultant of an entity that is presently engaged or is
10 planning to engage in the research, development, distribution, manufacture or sale
11 of any product that competes with or is in the same therapeutic class with any
12 product researched, developed, manufactured or sold by the Producing Party unless
13 the party seeking to provide or disclose such information to such persons obtains
14 the express written consent of counsel for the Producing Party or obtains an order
15 from the Court permitting the disclosure. Any party may object to compliance
16 with this provision in writing, stating the grounds and serving a copy of such
17 objection on all parties. The parties will meet and confer in good faith to resolve
18 the objection if possible in accordance with Local Rule 37-1. If the objection
19 cannot be resolved, the dispute shall be submitted to the Court pursuant to Local
20 Rule 37-2 for a ruling on the issue before disclosure of information to any person
21 who falls within the provisions of this paragraph.

22 26. Nothing in this Order shall be deemed to preclude the Defendants
23 from disclosing to the Food and Drug Administration, or any other regulatory
24 authority, Confidential Discovery Material or information gleaned from
25 Confidential Discovery Material, as may be required by statute or regulation.

26 27. Any party objecting to any designation of a Document as Confidential
27 Discovery Material and/or Confidential Personal Information, may at any time
28 prior to the close of discovery in this action serve upon counsel for interested

1 parties a written notice stating with particularity all good faith litigation driven
2 reasons for the objection. The parties shall make good faith efforts to resolve any
3 dispute with opposing counsel, including meeting and conferring with counsel for
4 the Producing Party regarding the designation of individual Documents pursuant to
5 Local Rule 37-1. If agreement cannot be reached, the dispute will be submitted to
6 the Court in accordance with Local Rule 37-1 and 37-2, and the party seeking to
7 challenge the designation shall bear the burden of demonstrating that the challenge
8 is made in good faith and is litigation driven. Pending resolution of the dispute by
9 the Court, the material designated as Confidential Discovery Material and/or
10 Confidential Personal Information shall remain so designated pursuant to this
11 Protective Order.

12 28. If another court or an administrative agency subpoenas or otherwise
13 orders production of Confidential Discovery Material and/or Confidential Personal
14 Information, which any party or other person has obtained under the terms of this
15 Order, the party or other person to whom the subpoena or other process is directed
16 shall immediately notify the Producing Party in writing of the following: (1) the
17 Confidential Discovery Material and/or Confidential Personal Information that are
18 requested for production in the subpoena; (2) the date on which compliance with
19 the subpoena is requested; (3) the location at which compliance with the subpoena
20 is requested; (4) the identity of the party serving the subpoena and all available
21 contact information for the serving party's counsel; and (5) the case name,
22 jurisdiction and index, docket, complaint, charge, civil action or other
23 identification number, or other designation identifying the litigation, administrative
24 proceeding or other proceeding in which the subpoena or other process has been
25 issued. The subpoenaed party or person shall not produce Confidential Discovery
26 Material or Confidential Personal Information prior to providing the Producing
27 Party written notice of the request and confirming receipt of same, at which time
28 the Producing Party bears the burden (and all costs) of opposing the subpoena or

1 other notice as it deems appropriate. The party receiving the subpoena or other
2 notice shall cooperate with the Producing Party in any proceeding relating thereto.
3 Nothing in this Order shall be construed as authorizing a party to disobey a lawful
4 subpoena issued in another action.

5 29. Documents that have been designated as Confidential Discovery
6 Material and/or Confidential Personal Information pursuant to the provisions of
7 this Order and that are to be filed with the Court shall be accompanied by an
8 application pursuant to Local Rule 79-5.1. Portions of any pleading, declaration,
9 or other material submitted to the Court that quotes, incorporates, reflects or
10 otherwise includes, in whole or in part Confidential Discovery Material and/or
11 Confidential Personal Information shall also be accompanied by an application
12 pursuant to Local Rule 79-5.1. The application shall be directed to the judge to
13 whom the papers are directed. Pending the ruling on the application, the papers or
14 portions thereof subject to the sealing application shall be lodged under seal,

15 30. The provisions of this Order shall not terminate at the conclusion of
16 this action. Except as otherwise expressly provided in this Order, within thirty (30)
17 days after final conclusion of the last case in the Litigation, or such other time as
18 the Producing Party may agree in writing, counsel shall, at their option, return or
19 destroy all Documents (including without limitation any and all Electronic
20 Discovery Material) designated as containing Confidential Discovery Material
21 and/or Confidential Personal Information, and all copies thereof. If counsel elects
22 to destroy Confidential Discovery Material and/or Confidential Personal
23 Information, they shall consult with counsel for the Producing Party on the manner
24 of destruction and obtain such Party's consent as to the method and means of
25 destruction. Each party shall certify, in writing, as to such return or destruction of
26 the Confidential Discovery Material and/or Confidential Personal Information
27 within the 30-day period. The parties shall petition the Court to order the Clerk to
28 return any Confidential Discovery Material and/or Confidential Personal

1 Information filed under seal. Outside counsel, however, shall not be required to
2 return or destroy any pretrial or trial records that are regularly maintained by that
3 counsel in the ordinary course of business; which records will continue to be
4 maintained as Confidential Discovery Material and/or Confidential Personal
5 Information in conformity with this Order, and which include: privileged
6 communications, work product, signed copies of the Acknowledgement of
7 Stipulated Protective Order, and all court-filed documents even though they
8 contain Confidential Discovery Material and/or Confidential Personal Information,
9 but such Documents shall remain subject to the terms of this Protective Order.

10 31. The Court shall retain jurisdiction over all persons and parties subject
11 to this Protective Order to the extent necessary to modify this Protective Order,
12 enforce its obligations, or to impose sanctions for any violation.

13 32. Nothing in this Protective Order shall prevent any party from seeking
14 further or additional protection for, or removing protection from, Confidential
15 Discovery Material and/or Confidential Personal Information, even if the terms are
16 contrary to this agreed Order.

17 33. Additional parties may be added to the Litigation as allowed under the
18 applicable Rules of Civil Procedure. Before receiving Confidential Discovery
19 Material or Confidential Personal Information, a new party to the Litigation and its
20 counsel must agree to be bound by the terms of this Protective Order as if the party
21 had stipulated to it at the time of entry, at which time the party shall be considered
22 a "party" to this Protective Order. No newly-added party to the Litigation or its
23 counsel shall have access to Confidential Discovery Material or Confidential
24 Personal Information until the newly-added party to the Litigation, its counsel are
25 subject to the terms of this Protective Order.

26 34. This Protective Order shall not apply to, or restrict, Confidential
27 Discovery Material or Confidential Personal Information used at the time of trial as
28 evidence. Protection of Confidential Discovery Material and/or Confidential

1 Personal Information at trial may be addressed by the Court as a separate matter
2 upon the motion of any party. The provisions of this Protective Order shall not
3 prejudice the rights of the parties with respect to the use or protection of
4 Confidential Discovery Material or Confidential Personal Information at trial.

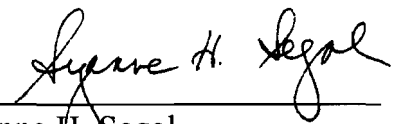
5 35. Nothing in this Protective Order shall preclude a party from using or
6 disclosing its own Confidential Discovery Material or Confidential Personal
7 Information in any manner it sees fit, without the prior consent of any other party
8 and without waiving its confidentiality status under this Protective Order.

9 36. Each person who has access to Confidential Discovery Material
10 and/or Confidential Personal Information shall take all due precautions to prevent
11 the unauthorized or inadvertent disclosure of the material.

12 37. A party who learns of an unauthorized disclosure of Confidential
13 Discovery Material and/or Confidential Personal Information by it or by any
14 person to whom the party has disclosed such information pursuant to this
15 Protective Order shall immediately (a) issue written notice of the unauthorized
16 disclosure to the Producing Party; (b) use best efforts to retrieve all copies of the
17 Confidential Discovery Material and/or Confidential Personal Information subject
18 to unauthorized disclosure; (c) inform all persons to whom unauthorized disclosure
19 was made of the terms of this Protective Order; and (d) use best efforts to secure an
20 Acknowledgement of Stipulated Protective Order from all persons to whom the
21 unauthorized disclosure was made.

22 38. This Protective Order may be modified by the Court upon motion
23 filed pursuant to Central District Local Rule 37 or by stipulation of the parties
24 approved by further order of the Court .

25 Dated: 4/15/13

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27 Suzanne H. Segal
28 United States Chief Magistrate Judge

1 Distribution:
2 All Counsel of Record
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EXHIBIT 1**ACKNOWLEDGEMENT OF STIPULATED PROTECTIVE ORDER**

I, _____, acknowledge that I have received and understand the Stipulated Protective Order ("Protective Order") in this action governing the non-disclosure of those portions of discovery material that have been designated as Confidential ("Confidential Discovery Material"), and/or as Personal Information or Sensitive Personal Information ("Confidential Personal Information") or contain individually identifiable health information. I agree that I will not disclose such Confidential Discovery Material or Confidential Personal Information to anyone other than for purposes of the Litigation and that at the conclusion of the Litigation I will return all such Confidential Discovery Material and Confidential Personal Information to the party or attorney from whom I received it. By acknowledging these obligations under the Protective Order, I understand that I am submitting myself to the jurisdiction of the State of California for the purpose of any issue or dispute arising hereunder and that my willful violation of any term of the Protective Order could subject me to punishment for contempt of Court.

Dated this _____ day of _____, _____.
